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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,620	12/22/2003	Barbara E. Blum	702.163	7396

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WRIGHT MEDICAL TECHNOLOGY, INC.
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EXAMINER

SCHUBERG, LAURA J

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/743,620

Applicant(s)

BLUM ET AL.

Examiner

Laura Schuberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/14/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) 1 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/22/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention II (claims 5-11) in the reply filed on 07/14/2006 is acknowledged. The traversal is on the ground(s) that the inventions, particularly in view of the amendments, are not patentably distinct. Applicant's arguments are found persuasive and the restriction requirements have been withdrawn.

Claims 1-11 are pending and have been examined on the merits.

Claim Objections

Claims 1 and 5 are objected to because of the following informalities: DBM and BMP should be spelled out, at least initially, for purposes of clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The tradename ELISA is used improperly as a limitation in the claim (MPEP 2173.05 (u)).

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the

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requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5, 6, 8-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Han et al (Journal of Orthopaedic Research 2003).

Claim 5 is drawn to a process for determining osteoinductivity of DBM via assay of BMP, comprising: providing DBM; solubilizing BMP from the DBM to thereby obtain an unfiltered BMP containing solution; assaying the unfiltered BMP containing solution to determine a level of a selected BMP in the unfiltered BMP solution.

Claim 6 further comprises comparing the level of the selected BMP to data correlating BMP level with osteoinductivity to thereby predict osteoinductivity of the DBM.

Claim 7 further includes wherein the assay of the selected BMP is conducted with an ELISA kit.

Claim 8 further includes wherein the molecules having a molecular weight of less than 10kDa are retained in the BMP containing solution during the assay for BMP.

Claim 9 includes wherein the selected BMP is BMP-2.

Claim 10 includes wherein the level of the BMP-2 in the BMP containing solution is greater than about 1400 pg/g DBM.

Claim 11 further comprises implanting a portion of the DBM into at least one rat to determine a level of new bone growth induced by the DBM and correlating the level of new bone growth with the level of the selected BMP in the unfiltered DBM containing solution to obtain data correlating BMP level of the DBM with osteoinductivity of the DBM.

Han teaches a process for determining osteoinductivity of DBM via in vitro assay of BMP comprising extracting one gram of DBM with guanidine-HCl; rinsing with distilled water; air dried; and assayed for BMP-2 (page 649 materials and methods) (claims 5

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and 9). Since a filtering step is not taught, the BMP is interpreted as unfiltered.

Comparison of BMP level to data correlating BMP level with osteoinductivity to predict osteoinductivity of the DBM is also taught as well as wherein the level of the BMP-2 in the BMP containing solution is greater than about 1400 pg/g DBM (page 650 figure 1) (claims 6 and 10). Han also teaches the use of athymic nude rats for an in vivo assay of the osteoinductivity of DBM (page 649 nude rat model) (claim 11). Wherein the molecules having a molecular weight of less than 10 kD are retained in the BMP containing solution during the assay for BMP is deemed to be inherent since Applicant states that these small molecules are present if the sample is not dialyzed (page 11), which Han doesn't (claim 8).

Therefore, Han anticipates Applicant's invention as claimed.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Wironen et al (US 2003/0008328 A1).

Claim 1 is drawn to a process for determining osteoinductivity of DBM via assay of BMP, comprising: providing DBM; mixing a first portion of DBM with an aqueous solution of a neutral salt and a solubilizing agent for BMP to obtain an unfiltered BMP containing liquid fraction; assaying BMP from the resulting liquid fraction with an ELISA kit to determine osteoinductivity without dialyzing the liquid fraction.

Claim 2 further comprises taking a second portion of the DBM and determining its osteoinductivity by implantation in an athymic nude rat.

Claim 3 further includes wherein the solubilizing agent is collagenase.

Claim 4 further includes the step of retaining molecules having a molecular weight of less than 10kDa.

Claim 7 is drawn to the method of claim 5 and further includes wherein the assay of the selected BMP is conducted with an ELISA kit.

Wironen teaches a process for determining osteoinductivity of DBM via in vitro assay of BMP which includes mixing a first portion of DBM with an aqueous solution of a neutral salt and collagenase and assaying with an ELISA kit the BMP from the resulting fraction without dialyzing the liquid fraction (page 5 para 51). While Wironen does teach the steps of filtering or dialyzing, they are clearly taught as optional steps (page 5 para 52), thus allowing for an embodiment that comprises assaying unfiltered BMP with collagenase (page 9 claim 7) (claims 1, 3, 5, 7). Wherein the BMP is BMP-2 is taught (page 5 para 53) as well as wherein the level of the BMP-2 is greater than about 1400 pg/g DBM (page 6 example 2) (claims 9-10). Comparison of BMP level to data correlating BMP level with osteoinductivity to predict osteoinductivity of the DBM is also taught as well as the use of athymic nude rats for an in vivo assay of the osteoinductivity of DBM (page 6 para 56) (claims 2, 6 and 11). Wherein the molecules having a molecular weight of less than 10 kD are retained in the BMP containing solution during the assay for BMP is deemed to be inherent since Applicant states that these small molecules are present if the sample is not dialyzed (page 11), which Wironen teaches is optional (claims 4 and 8).

Therefore, Wironen anticipates Applicant's invention as claimed.

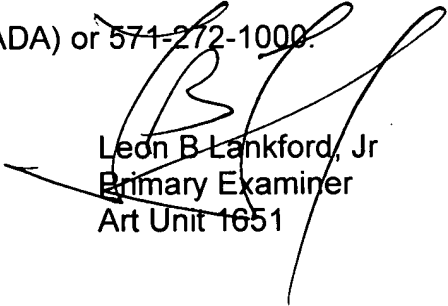
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B Lankford, Jr
Primary Examiner
Art Unit 1651

Laura Schuberg